

### **REMARKS**

In the Office Action dated June 2, 2004, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents the following six separate and distinct inventions:

- I. Claims 1-10, drawn to a method for "treating diseases caused by and/or associated with an altered protein kinase activity", classified variously in class 514, subclass 403, 406, 407 depending on the structure of the derivative and its use.
- II. Claims 11, drawn to a method for "inhibiting protein kinase" activity, classified variously in class 435, subclass 7.1.
- III. Claims 12-20 and 26, drawn to a product described as a "hydroxyaryl-pyrazole derivative" represented by formula (I), classified variously in class 548, subclass 373.1, 377.1 depending on the structure of the compound and its use.
- IV. Claims 21 and 27, drawn to a method of making "compounds of formula (I) or the pharmaceutically acceptable salts thereof", classified variously in class 546, subclass 275.4 depending on the structure of the compound and the method steps used to make said compound.
- V. Claim 22, drawn to a product described as a "library of two or more compounds of formula (I)", classified variously in 435, subclass 6, DIG 34.
- VI. Claim 23-25, drawn to a product described as a "pharmaceutical composition comprising a therapeutically effective amount of a compound of formula (I)" or a "combined preparation for simultaneous separate or sequential use in anticancer therapy, classified variously in class 424, subclass 455, subclass 464+.

The Examiner also required if Group III was to be elected, that Applicants elect a species from formula I in Claim 12.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Group III, Claims 12-20 and 26, drawn to a product described as a "hydroxyaryl-pyrazole derivative" represented by formula (I), classified variously in class 548, subclass 373.1, 377.1 depending on the structure of the compound and its use. Applicants further elect the following species:

“5-cyclopropyl-N-ethyl-3-(2-hydroxy-5-methylphenyl)-1H-pyrazole-1-carboxamide”

Applicants respectfully submit that claims 12-20 and 26 are readable on the elected species.

Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicants hereby traverse the Examiner’s requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner’s authority to require restriction is defined and limited by statute:

If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement.

The Examiner has asserted that Groups I-II, and IV are drawn to different methods and that Groups III and V-VI are drawn to different products. Applicants respectfully traverse.

Groups I-VI are related, and all represent different aspects of the same invention. Group III relates to compounds of formula I, Group IV is drawn to a method of making a compound of formula I, Group V relates to a library containing two or more compounds of formula I, Group VI relates to pharmaceutical compositions of formula I, and Groups I and II relate to methods of using the compounds of formula I.

The Examiner has not shown that the compounds of formula I can be used on a materially different process of using this product. The compounds of formula I are all kinase inhibitors and kinase inhibitors can be used in the methods to treat the indications in claims 1-10. Kinase inhibitors of formula I can also be used to inhibit protein kinase activity as claimed in Claim 12. Accordingly, the kinase inhibitors of the claimed invention are not being used on materially different processes.

The Examiner has also not shown that the process of using the claimed compounds can be used on another compound with a materially different structure.

MPEP §806.05(h) explicitly places the burden on the Examiner to provide an example to show that the claims to a product and to their methods of use are patentably distinct inventions. The Examiner has not met the burden of showing that the claims of Groups I and VI are distinct inventions.

Accordingly, Applicants respectfully request that this restriction requirement be removed.

The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

The Examiner also states that the inventions have acquired a separate status in the art as evidenced by the separate classification and recognized divergent subject matter and would

require independent searches. Thus, the Examiner concludes that restriction for examination purposes is proper.

Reliance on the supposed classification of the groups of claims does not establish independence and distinctness. The classification system has no statutory recognition as evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of applicants' unitary invention, because the system exhibits considerable overlap in technical definitions. In particular, the definitions of classes and subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims assigned to one group, on patent references found in the classes or subclass(es) with which he associated another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change, thereby casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience, and often in response to nothing more than growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patents assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.C. §121, which fact proves that basing restriction requirements on the classification system is improper.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade

and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined groups, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Peter I. Bernstein', written over the printed name.

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